Retrieve Data

Reset Form

Principal Investigator: _____ Laboratory building: _____ Laboratory room number(s): _____ Date: _____

Additional PI's: 1)_____ 2)_____ 3)_____ 4)_____ 5)_____

SECTION 5 – LABORATORY INFORMATION
(COMPLETED BY EACH PRINCIPAL INVESTIGATOR AND APPROVED BY THE RO)

Provide the following information for each Principal Investigator working with select agents and toxins at your entity. Make additional copies of this section of the form as needed. Each principal investigator should complete questions 1 through 87, as appropriate for *each* laboratory room where select agents are used or stored. Incomplete answers will delay processing the application. In the "facility agent ID" column indicate any identification used to identify a specific agent or toxin or derivatives of these (i.e., EEE-p102 to identify a modified strain of EEE that is unique to your laboratory).

SECTION 5A – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR

Include a current resume or Curriculum Vitae from the principal investigator.

1. Name of individual responsible for the laboratory (e.g., principal investigator): _____
2. Provide the following information for each agent(s) worked with or stored in the laboratory building(s) and room(s):

Reset Radio Buttons

AGENT/TOXIN NAME	STRAIN DESIGNATION	DATE ACQUIRED (list N/A if not acquired)	ADDRESS OF FACILITY FROM WHICH THE AGENT/TOXIN WAS ACQUIRED (Include registration number if applicable)	FACILITY AGENT I.D.	SOURCE OF ISOLATE			UNIQUE DIAGNOSTIC CHARACTERISTICS	REFERENCE FOR PUBLISHED SEQUENCE INFORMATION (GenBank accession number, journal articles, etc.)
					Clinical	Environmental	Other (explain)		
					☐	☐			
					☐	☐			
					☐	☐			
					☐	☐			
					☐	☐			
					☐	☐			
					☐	☐			
					☐	☐			

Save Data

Next Page

Duplicate This Page

Previous Page

Principal Investigator: _____ Laboratory building: _____ Laboratory room number(s): _____ Date: _____

Additional PI's: 1)_____ 2)_____ 3)_____ 4)_____ 5)_____

SECTION 5A – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR (Continued)

Make additional copies of this section of the form as needed for *each* laboratory room for each principal investigator at your entity. Each principal investigator should complete questions 3 through 77, as appropriate for *each* laboratory where select agents are used or stored. If all laboratories with the same biosafety level under the control of one principal investigator meet the same criteria, then list all laboratory rooms and submit only one form. Include a floor plan for each laboratory where agents or toxins are to be used or stored (for all biosafety levels).

3. Floor plan(s) include:
   - a. Sink locations ☐ Yes ☐ No
   - b. Eyewash locations ☐ Yes ☐ No
   - c. Biological safety cabinet (BSC) locations ☐ Yes ☐ No
   - d. Fume hood locations ☐ Yes ☐ No
   - e. HVAC supply and exhaust locations ☐ Yes ☐ No
   - f. Freezer/refrigerator locations ☐ Yes ☐ No
   - g. Other large equipment locations (incubators, centrifuges, etc) ☐ Yes ☐ No

4. Provide a description of the HVAC system (*check all that are appropriate*):
   - a. ☐ Single-pass ☐ Re-circulated
   - b. ☐ Dedicated exhaust ☐ Shared exhaust
   - c. ☐ Constant air volume ☐ Variable air volume
   - d. ☐ Redundant exhaust fans
   - e. ☐ Emergency power back-up

5. Provide information on the biological safety cabinets in use (attach additional sheets if needed):
   - a. Class of cabinet: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ III
   - b. Biological safety cabinet connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating
   - c. Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain):_____
   - d. Does user verify air inflow during BSC use? ☐ Yes ☐ No

6. **NOTE**: If your entity has a BSL-4 or ABSL-4 laboratory, then skip to Section 6 and complete Sections 6A and 6B, and any other sections that are applicable to your entity.

7. BSL-3 laboratory registration must answer the following:
   - a. Entry into the lab is through a double set of lockable self-closing doors: ☐ Yes ☐ No
   - b. Each laboratory room has a hands-free sink: ☐ Yes ☐ No
   - c. An eyewash station is readily available inside the laboratory: ☐ Yes ☐ No
   - d. There is an autoclave or other verified or approved method for decontamination within the laboratory: ☐ Yes ☐ No
   - e. If no autoclave in the BSL-3 laboratory, describe waste handling protocols to be used by the laboratory personnel:
   - f. Laboratory exhaust is re-circulated to other areas of the facility: ☐ Yes ☐ No
   - g. The laboratory is maintained at negative air pressure to provide directional air into the laboratory: ☐ Yes ☐ No
   - h. A visual system is provided for laboratory personnel to monitor directional air before entry and during use of the laboratory: ☐ Yes ☐ No
   - i. An alarm system is provided to warn laboratory personnel of exhaust system failure: ☐ Yes ☐ No
   - j. HEPA filtration of all exhaust air is in place: ☐ Yes ☐ No

Save Data Next Page

Previous Page

Principal Investigator: _____ Laboratory building: _____ Laboratory room number(s): _____ Date: _____

Additional PI's: 1)_____ 2)_____ 3)_____ 4)_____ 5)_____

8. ABSL-2 laboratory registration must answer the following:

a. Animal laboratories are separated from open and unrestricted areas: ☐ Yes ☐ No

b. Animal laboratory exhaust is re-circulated to other areas of the facility: ☐ Yes ☐ No

c. The animal laboratory is maintained at negative air pressure to provide directional air into the animal laboratory: ☐ Yes ☐ No

d. There is an autoclave in the laboratory: ☐ Yes ☐ No

e. External doors are self-closing, self-locking, and open inward: ☐ Yes ☐ No

f. Cage washing is: ☐ Manual ☐ With a mechanical cage washer

g. The cage washing area is shown on attached floor plan: ☐ Yes ☐ No

h. Each animal room where infected animals are kept contains a hand-washing sink: ☐ Yes ☐ No

i. If floor drains are provided, the traps are always filled with an appropriate disinfectant: ☐ Yes ☐ No

9. ABSL-3 laboratory registration must include the following:

a. Animal laboratories are separated from open and unrestricted areas: ☐ Yes ☐ No

b. Entry into the animal lab is through a double set of lockable self-closing doors: ☐ Yes ☐ No

c. External doors are self-closing, self-locking, and open inward: ☐ Yes ☐ No

d. Each animal room contains a hands-free hand washing sink: ☐ Yes ☐ No

e. Animal laboratory exhaust is re-circulated to other areas of the entity: ☐ Yes ☐ No

f. The animal laboratory is maintained at negative air pressure to provide directional air into the animal laboratory: ☐ Yes ☐ No

g. A visual system is provided for laboratory personnel to monitor directional air before entry and during use of the animal laboratory: ☐ Yes ☐ No

h. An alarm system is provided to warn laboratory personnel of exhaust system failure: ☐ Yes ☐ No

i. HEPA filtration of all exhaust air is present: ☐ Yes ☐ No

j. There is an autoclave in the laboratory: ☐ Yes ☐ No

k. Cage washing is with a mechanical cage washer: ☐ Yes ☐ No

l. Cage washing area is shown on the floor plans: ☐ Yes ☐ No

m. Animal waste treated (carcasses, sewage, bedding, etc.) before disposal ☐ Yes ☐ No

If yes describe treatment method: _____

n. If floor drains are provided, the traps are always filled with an appropriate disinfectant: ☐ Yes ☐ No

ALL LABORATORIES MUST ANSWER THE FOLLOWING:

10. Laboratory is currently operational: ☐ Yes ☐ No

If no, date of anticipated completion of laboratory: _____

11. Appropriate personal protective equipment is used: ☐ Yes ☐ No

12. Vacuum lines contain HEPA filters: ☐ Yes ☐ No ☐ No vacuum lines are used

13. Each laboratory using select agents has an agent-specific, site-specific biosafety manual: ☐ Yes ☐ No

14. A medical surveillance system is in place for laboratory personnel using select agents: ☐ Yes ☐ No

15. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director: ☐ Yes ☐ No

16. A sharps policy is in place for this laboratory (or laboratories): ☐ Yes ☐ No

17. A site-specific emergency operations plan is available for this laboratory: ☐ Yes ☐ No

Save Data Next Page

Previous Page

Principal Investigator: _____ Laboratory building: _____ Laboratory room number(s): _____ Date: _____

Additional PI's: 1)_____ 2)_____ 3)_____ 4)_____ 5)_____

18. An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with select agents at this facility? ☐ Yes ☐ No

    a. If yes, has IBC approved the work proposed in this application: ☐ Yes ☐ No

    b. The facility has been inspected by USDA, FDA, CLIA, DoE, DoD or others: ☐ Yes ☐ No

    c. If yes, then give agency and date of last inspection(s): _____

19. Briefly state (no more than a paragraph) the objectives of the work with the select agent(s), including a description of the methodologies or laboratory procedures that will be used. State if any host-vector systems will be used. Specify whether work will involve live agents and recombinant DNA:

_____

SECTION 5B – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR (TRAINING AND SECURITY)

20. Training:

    a. Site specific security and safety training is provided to individuals with access to areas where select agents are handled or stored: ☐ Yes ☐ No

    b. Is provided prior to individuals beginning to work with select agents: ☐ Yes ☐ No

    c. Is provided: ☐ Annually ☐ Biannually ☐ Other (specify frequency): _____

    d. Written records of individuals trained are kept: ☐ Yes ☐ No

    e. Personnel demonstrate proficiency in laboratory procedures prior to working with select agents: ☐ Yes ☐ No

    f. Provide a brief description of what is included in the training program:

_____

21. Provide a brief explanation of the system in place to detect loss or theft of select agent(s):

_____

    a. Individual responsible for inventory of select agent(s):

_____

    b. How often is the inventory record reconciled?

_____

    c. How is access to the inventory log limited?

_____

    d. Inventory tracking includes the following information (list):

_____

22. There is a site-specific security plan for each of the laboratories listed above in Section 5A (number 2): ☐ Yes ☐ No

    a. Building with select agents has self-closing doors: ☐ Yes ☐ No

Save Data Next Page

Previous Page

Principal Investigator: _____ Laboratory building: _____ Laboratory room number(s): _____ Date: _____

Additional PI's: 1)_____ 2)_____ 3)_____ 4)_____ 5)_____

b. Means to limit access to buildings with laboratories with select agents:
- ☐ Guard station at the entity entrance
- ☐ Card access system or locks
- ☐ Security alarm system in the laboratory building
- ☐ Other (describe): _____

c. Means to limit access to laboratories with select agents once inside the building:
- ☐ Door to laboratory is locked
- ☐ Guard station at the building entrance
- ☐ Card access system or locks
- ☐ Security alarm system in the laboratory
- ☐ Other (describe): _____

d. Means to limit access to select agents once inside the laboratory:
- ☐ Locked incubators, refrigerators, freezers, etc.
- ☐ Security alarm system that directly monitors the laboratory
- ☐ Other (describe): _____

e. Means to limit access to select agents in storage:
- ☐ Storage area door locked
- ☐ Lock boxes
- ☐ Security alarm system that directly monitors the laboratory
- ☐ Other (describe): _____

f. Means to monitor unauthorized entry into the laboratory where select agents are used or stored:
- ☐ Electronic logs of card access system entries are reviewed for unusual activity
- ☐ Manual sign in and out logs are kept and monitored
- ☐ Video camera surveillance
- ☐ Other (describe): _____

g. The laboratory is secured when no one is present during regular working hours: ☐ Yes ☐ No

h. Individuals not directly involved in research activities have access to select agents: ☐ Yes ☐ No

If yes, please explain:_____

i. Non-laboratory personnel (visitors, including janitorial and entity maintenance personnel) have access to the laboratory with select agents: ☐ Yes ☐ No

If yes, are they allowed into the laboratory unescorted? ☐ Yes ☐ No

j. Provide additional details regarding how the entity limits access to the laboratories where select agents are being manipulated and stored to only authorized and qualified persons (add additional sheets as necessary):

_____

SECTION 5C –TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH INFECTIOUS AGENTS

23. Provide an estimate of the maximum quantities (e.g., number of petri dishes or total volume of liquid media) and concentration of each organisms grown at a given time (e.g., 2 - 250 ml flasks of 10^5 cfu/ml):

_____

24. All cultures, stock and other regulated wastes are decontaminated before disposal by an approved decontamination method: Yes ☐ No ☐

a. If yes, describe method:_____

Save Data Next Page

Previous Page

Principal Investigator: _____ Laboratory building: _____ Laboratory room number(s): _____ Date: _____

Additional PI's: 1)_____ 2)_____ 3)_____ 4)_____ 5)_____

SECTION 5D – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH RECOMBINANT DNA OR GENOMIC MATERIAL

25. The entity has an Institutional Biosafety Committee that has approved work with recombinant DNA or has approval pending: ☐ Yes ☐ No
26. The biosafety level listed in Section 4A for this laboratory meets NIH guidelines: ☐ Yes ☐ No
27. Will you be possessing, using or transferring the following:
    a. Nucleic acids that can produce infectious forms of any of the select agent viruses. ☐ Yes ☐ No
    b. Recombinant nucleic acids that encode for the functional form(s) of any select toxins if the nucleic acids:
        1) can be expressed in vivo or in vitro. ☐ Yes ☐ No
        2) are in a vector or recombinant host genome and can be expressed in vivo or in vitro. ☐ Yes ☐ No
    c. Select agent viruses, bacteria, fungi, and toxins that have been genetically modified. ☐ Yes ☐ No
28. Are you intending to conduct the following experiments:
    a. Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture. ☐ Yes ☐ No
    b. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD_{50} < 100 ng/kg body weight. ☐ Yes ☐ No
29. Provide a brief description of the recombinant constructs and any associated expression control elements, including what the recombinant DNA encodes for, if known: _____
30. Give an estimate of range of length of recombinant DNA to be used: _____

SECTION 5E – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH SMALL ANIMALS

31. List species of small animals that will be used: _____
32. Describe route of infection: _____
33. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐ Yes ☐ No
    a. If yes, describe method:_____
34. The entity requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this entity: ☐ Yes ☐ No
    a. If yes, the proposed work with select agents in small animals has been approved by the IACUC: ☐ Yes ☐ No
35. The laboratory is accredited by AAALAC: ☐ Yes ☐ No
    a. If yes, give accreditation date: _____

SECTION 5F – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH LARGE ANIMALS

36. List species of large animals that will be used: _____
37. Describe route of infection: _____
38. Carcass of animals are disposed in a manner to preclude their use as food for human beings or animals ☐ Yes ☐ No
39. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐ Yes ☐ No
    a. If yes, give method:_____
40. Carcass of animals are disposed of on site: ☐ Yes ☐ No
41. The entity requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this entity: ☐ Yes ☐ No
    a. If yes, the proposed work with select agents in large animals has been approved by the IACUC: ☐ Yes ☐ No

Save Data Next Page

Previous Page

Principal Investigator: _____ Laboratory building: _____ Laboratory room number(s): _____ Date: _____

Additional PI's: 1)_____ 2)_____ 3)_____ 4)_____ 5)_____

42. The laboratory is accredited by AAALAC: ☐ Yes ☐ No

a. If yes, give accreditation date: _____

SECTION 5G – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH TOXINS

43. A Chemical Hygiene Plan is available for the laboratory using toxins: ☐ Yes ☐ No

44. Maximum quantity of each toxin under the control of the principal investigator at a given time: _____

45. Form of toxins used: ☐ Liquid ☐ Lyophilized ☐ Not Applicable-Storage Only

46. The toxin is produced by live agent at the entity: ☐ Yes ☐ No

a. If yes, provide a brief description of procedures used (include an estimate of the maximum quantities grown at a given time): _____

47. Dilution procedures and other manipulations of the concentrated toxins are:

a. Conducted in: ☐ Fume hood ☐ Biological safety cabinet ☐ Not Applicable-Storage Only

1) If a fume hood or biosafety cabinet is used, certification is conducted:
☐ Annually ☐ Biannually ☐ Other (describe): _____

b. Work is conducted with two knowledgeable people present: ☐ Yes ☐ No

48. A hazard sign is posted on the door when toxins are present: ☐ Yes ☐ No

Save Data Print Email Form